

Remarks

1-13, 18, 19, 21-23 and 34-52 are pending in the subject application. By this Amendment, claims 1, 3, 8, 10, 12, 18, 19, 21 and 22 have been amended and claims 14-17, 24-27, 40-42 and 53-59 have been cancelled. No new matter has been added by these amendments. Accordingly, claims 1-13, 18, 19, 21-23, 34-39 and 43-52 are before the Examiner for consideration.

The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. The amendments should not be taken to indicate the applicant's agreement with, or acquiescence to, the rejection of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein is earnestly solicited.

The applicants submitted an electronic Communication and Revocation and Power of Attorney and New Power of Attorney to the Patent Office on April 24, 2009, copy attached. The applicants respectfully request that the subject application be updated to show the correct customer number and attorneys of record.

The applicants gratefully acknowledge the Examiner's withdrawal of the objections and rejections under 35 U.S.C. § 112, first paragraph and 35 USC §102(b).

Claims 1-5, 7, 8, 10, 12, 18, 19, 23, 34-38, and 44-52 have been rejected under 35 U.S.C. §102(b) as being anticipated by Clancy *et al.* (2000, *Infection and Immunity* 68(5):2621-2629). The applicants respectfully traverse this ground for rejection because the cited reference does not disclose each and every element of the claimed invention. Specifically, the recombinant bacterial cell of Clancy *et al.* does not have heterologous DNA encoding a nickel transporter as is required by the applicants' claims.

In order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of

the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman v. Kimberly-Clarke*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

Claims 1 and 34 are drawn to a recombinant bacterial cell that, among other things, expresses at least one alkalizing enzyme and nickel transporter from heterologous DNA. Thus, the claimed recombinant bacterial cell expresses at least one nickel transporter gene, such as *ureMQO*. As a result, active urease activity can be obtained without the need for supplementing the growth medium with Ni^{2+} , which is toxic to humans.

The Clancy *et al.* reference does not disclose the present invention because the recombinant bacterial cell in Clancy *et al.* does not express a nickel transporter from heterologous DNA.

The Clancy *et al.* reference, upon which Dr. Burne is a co-author, discloses a urease-expressing *S. mutans*. As is explained in the accompanying Expert Declaration of Dr. Burne, the Clancy *et al.* strain contains the urease gene *ureABCEFGD*, but lacks heterologous DNA encoding a nickel transporter. (See the Declaration of Dr. Burne at page 2, and Clancy *et al.* at page 2624, left column, Figure 1 and Abstract).

Because the Clancy *et al.* recombinant bacteria do not express a nickel transporter, it was necessary to add substantial amounts of Ni^{2+} to supplement the growth medium in order to obtain active urease activity. (Clancy *et al.* at page 2624, stating that because the strains “lack the high-affinity transport proteins that are needed to scavenge sufficient Ni^{2+} from the environment,” NiCl_2 needs to be added to the growth medium in order to observe significant urease activity). In fact, the nickel transporter gene *ureMQO* was not even identified until well after the publication of the Clancy *et al.* reference.

Thus, the Clancy *et al.* reference does not teach every element of the rejected claims. Accordingly, the applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §102(b) based on Clancy *et al.*

Claims 1-6, 10, 11, 18, 19, 21, 38 and 52 have been rejected under 35 U.S.C. §102(a) as being anticipated by Dong *et al.* (2002, *Applied and Environmental Microbiology* 68(11):5549-5553). The applicants respectfully traverse this ground for rejection because the cited reference does

not disclose each and every element of the claimed invention. Specifically, the recombinant bacterial cell of Dong *et al.* does not have heterologous DNA encoding a nickel transporter as is required by the applicants' claims. Furthermore, the Dong *et al.* reference is not available as prior art against the current application.

The Dong *et al.* reference is not available as prior art in the current case because it is the applicants' own publication that appeared less than one year before the applicants' filing date. "[O]ne's own invention, whatever the form of disclosure to the public, may not be prior art against oneself, absent a statutory bar." *In re Facius*, 161 USPQ 294, 301 (CCPA 1969); and MPEP §715.01(c).

The Dong *et al.* publication is from November 2002 while the current application claims the benefit of the October 7, 2003 filing date of U.S. provisional application Serial No. 60/509,175. Thus, the Dong *et al.* publication appeared less than one year before the current applicants' filing date.

In the course of their research on recombinant alkalizing bacteria, the inventors of the currently-claimed invention have been assisted to varying degrees by several people, including Ms. Dong and Ms. Snyder, who are co-authors on the Dong *et al.* publication. Although Ms. Dong and Ms. Snyder were co-authors on the Dong *et al.* publication, they did not contribute to the conception of the invention claimed in the current patent application.

As is explained in the Declaration of Dr. Burne, both Ms. Dong and Ms. Snyder were students at the time of the research that was described in the cited reference. Ms. Dong and Ms. Snyder worked under the supervision of Drs. Burne and Chen. Specifically, their work involved assisting with a basic characterization of the elements regulating arginine deiminase in *S. gordonii*.

The efforts of Ms. Dong and Ms. Snyder were greatly appreciated and, accordingly, they were acknowledged as co-authors on the publication; however, they did not contribute to the conception of the invention claimed in the current patent application. Therefore, despite their helpful assistance, Ms. Dong and Ms. Snyder could not be listed as co-inventors on the subject application. Under the authority of *In re Facius*, the disclosure contained in the Dong *et al.* reference, the relevant portions

of which originated from only the applicants, cannot be used as a reference against the applicants' claimed invention.

Even if the Dong *et al.* reference were available as prior art, it would not anticipate the current claims. The Dong *et al.* reference is directed to a recombinant bacterial cell having the arginine deiminase gene cluster, encoding enzymes for arginine catabolism (see Dong *et al.* at, for example, Abstract and Figure 1). As is explained in the Declaration of Dr. Burne, the Dong *et al.* bacterial cells lack heterologous DNA encoding a nickel transporter.

Although Dong *et al.* briefly mention recombinant *S. mutans* at page 5552 (Functional analysis of ArcR, last paragraph), the entire discussion is directed to the Clancy *et al.* reference (Reference 14). As discussed above, the recombinant bacteria of Clancy *et al.* do not express a nickel transporter from heterologous DNA.

Thus, the Dong *et al.* reference does not teach every element of the applicants' claims. Accordingly, the applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §102(b) based on Dong *et al.*

Claim 23 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Dong *et al.* (2002, Applied and Environmental Microbiology 68(11):5549-5553) as applied to claims 1-6, 10, 11, 18, 19, 21, and 52 above. The applicants respectfully traverse this rejection because the Dong *et al.* reference is not available as prior art against the current applicants' claims. Furthermore, even if the Dong *et al.* reference were available as prior art it does not disclose or suggest the claimed invention.

As discussed above, the Dong *et al.* reference is not available as prior art in the current case because it is the applicants' own publication that appeared less than one year before the applicants' filing date.

Furthermore, all of the claim limitations must be taught or suggested by the prior art in order to establish a *prima facie* case of obviousness. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). The Dong *et al.* reference does not teach or suggest a recombinant bacterial cell expressing a nickel transporter from heterologous DNA. Accordingly, the applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a).

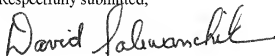
Claims 9, 13, and 39-43 have been objected to for depending on a rejected base claim. In view of the foregoing remarks and amendments to the claims, the applicants believe that the independent claims 1 and 34 are in condition for allowance; therefore, the applicants respectfully request reconsideration and withdrawal of this objection.

In view of the foregoing remarks and amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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DRS/la

Attachments: Declaration of Dr. Burne Under 37 CFR §1.132
Copy of Communication and Revocation of Power of Attorney and New Power of Attorney electronically submitted to the Patent Office on April 24, 2009